UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,089	05/01/2000	Michael Kerin McNamara	017227/0154	4665

7590 03/27/2002

Foley & Lardner
Suite 500
3000 K Street NW PO Box 25696
Washington, DC 20007-8696

EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/462,089	MCNAMARA, MICHAEL KERIN	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/7/00; 7/9/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *9-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-36 are pending.

2. Applicant's election with traverse of Group I, Claims 1-8, drawn to a composition, filed 7/9/01, is acknowledged. The traversal is on the grounds that (1) claims of groups I to VI possess unity if the special technical feature is common to all claims and (2) there is a single inventive concept in the novel composition. This is not found persuasive because of the reasons set forth in the restriction mailed 4/9/01.

The '688 patent (of record) teaches a composition comprising a LHRH-diphtheria toxoid conjugate for a contraceptive vaccine (See column 5, last paragraph bridging column 6, first paragraph, in particular). The '688 patent further teaches that conjugation of LHRH to the toxin is useful for destroying the gonadotrophs of the animal's anterior pituitary gland for sterilizing the animal (See abstract, in particular).

The claimed invention in claim 1 differs from the reference only by the recitation of said composition comprises an ionic polysaccharide wherein the polysaccharide is DEAE dextran.

The '596 patent (of record) teaches suitable adjuvant for the vaccination of animals and humans includes such as DEAE-dextran in a pharmaceutical composition comprising LHRH-TRATP fusion protein for inhibiting or controlling the reproductive function in vertebrate host (See column 5, lines 48-62, Abstract, in particular). Therefore, it would have been obvious to combine the suitable adjuvant such as DEAE-dextran as taught by the '596 patent with the LHRH-diphtheria toxoid conjugate as taught by the '688 patent for a contraceptive vaccine as taught by '688 patent and '596 patent.

Since applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention. Therefore, the requirement is still deemed proper and is therefore made FINAL.

3. Claims 9-36 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 1-8 are being acted upon in this Office Action.

5. Applicant should amend the first line of the specification to reflect the relationship between the instant application and PCT/AU98/00532 filed July 9, 1998 stated on the oath.

6. The disclosure is objected to because of the following informality: The arrangement of the specification. Appropriate correction is required.

7. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) *any* composition comprising *any* LHRH conjugated to diphtheria toxoid and an ionic polysaccharide wherein said ionic polysaccharide is DEAE-dextran wherein said LHRH is *any* LHRH 2-10 form, *any* modified LHRH 2-10 form and (2) *any* pharmaceutical composition comprising *any* LHRH conjugated to diphtheria toxoid wherein said LHRH is *any* LHRH 2-10 form, *any* modified LHRH 2-10 form and an ionic polysaccharide together with one or more pharmaceutically acceptable carrier and/or diluents wherein said ionic polysaccharide is DEAE-dextran for inhibits reproductive functions.

The specification discloses only a composition comprising a human LHRH-diphtheria toxoid conjugate wherein said human LHRH is selected from the group consisting of SEQ ID NO: 1, 2 and 3, and said modified human LHRH is consisting of SEQ ID NO: 4 and an ionic polysaccharide wherein said ionic polysaccharide is DEAE-dextran (2) a pharmaceutical composition comprising a human LHRH-diphtheria toxoid conjugate wherein said human LHRH is selected from the group consisting of SEQ ID NO: 1, 2 and 3, and said modified human LHRH is consisting of SEQ ID NO: 4 and an ionic polysaccharide together with one or more pharmaceutically acceptable carrier and/or diluents wherein said ionic polysaccharide is DEAE-dextran for inhibits reproductive functions.

Other than the specific LHRH peptide mentioned above conjugated to diphtheria toxoid for a contraceptive vaccine, there is insufficient written description about the structure associated with function of *any* LHRH, and *any* modified LHRH conjugated to diphtheria toxoid. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,378,688 (of record, Jan 1995, PTO 892) or Sad *et al* (Immunology74: 223-227 (1991, PTO 892) each in view of US Pat No. 5,614,487 (March 1997, PTO 892) or US Pat No. 5,5403,586 (of record, April 1995, PTO 892).

The '688 patent teaches a pharmaceutical composition comprising a LHRH-diphtheria toxoid conjugate for a contraceptive vaccine (See column 5, last paragraph bridging column 6, first paragraph, Claim 1 of '688 patent, in particular). The '688 patent teaches modified form of LHRH or analog such as the ones in Table on column 5, and a method of making said LHRH conjugate (See column 16, last paragraph, in particular). The '688 patent further teaches that conjugation of LHRH to toxin is useful for destroying the gonadotrophs of the animal's anterior pituitary gland for sterilizing the animal (See abstract, in particular). Claims 3 and 7 are included in this rejection because the '688 patent teach modified LHRH and analog of LHRH that comprises the C-terminal fragment of at least five amino acids of LHRH and amidated (having the NH_2 group) at the C-terminus (See column 8, lines 59-68, in particular), which is consistent with the definition of LHRH 2-10 form as disclosed on page 8 lines 6-9 of instant specification. Claims 4 and 8 are included in this rejection because the '688 patent further teaches modified form of LHRH 2-10 such as having amino acid substitution at the 6 and 10 positions of the LHRH peptide regardless of the nomenclature (See column 5, Superagonists, column 9, lines 25-41, in particular).

Sad et al teach a pharmaceutical composition comprising a GnRH which also known as LHRH conjugated to diphtheria toxoid (DT) in alumn (See page 224, column 1, first three full paragraphs, in particular).

The claimed invention in claims 1 and 6 differs from the reference only by the recitation of said composition comprises an ionic polysaccharide wherein said polysaccharide is DEAE dextran.

The '487 patent teaches a drug carrier such as dextran which is a polymer of glucose, also known as polysaccharide, containing vicinal diols that can be used for the sustained release of virtually any biologically active polypeptide (See abstract, column 3, lines 58-64, column 4, lines 15-30, in particular). The '487 patent teaches that dextrans have the advantages as drug carrier because of (1) high water solubility (ionic), (2) a well-defined and repetitive chemical structure, yielding many potential sites for binding or conjugation, (3) their availability in different molecular weight forms of from about $2x10^3$ to 10^6 and (4) low toxicity and inert (low pharmacological activity) (See column 4, lines 17-23, in particular).

The '596 patent (of record) teaches suitable adjuvant for the vaccination of animals and humans includes such as DEAE-dextran in a pharmaceutical composition comprising LHRH-TRATP fusion protein for inhibiting or controlling the reproductive function in vertebrate host (See column 5, lines 48-62, Abstract, in particular). The '596 patent further teaches vaccine composition may combined together with other carrier, diluents, excipient and/or adjuvant such as sterile water, Ringer's solution and isotonic sodium chloride solution (See column 5, 14-47, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the diphtheria toxoid conjugate for a contraceptive vaccine as taught by the '688 patent or substitute the alum as taught by Sad et al with the drug carrier such as polysaccharide dextran as taught by the '487 or the '596 patents.

One having ordinary skill in the art at the time the invention was made would have been motivated to do this because the '487 patent teaches the use of dextrans for the sustained release of virtually any biologically active polypeptide and dextrans have the advantages as drug carrier because of (1) high water solubility (ionic), (2) a well-defined and repetitive chemical structure, yielding many potential sites for binding or conjugation, (3) their availability in different molecular weight forms of from about $2x10^3$ to 10^6 and (4) low toxicity and inert (low pharmacological activity) (See column 4, lines 17-23, Abstract, in particular). The '596 patent (of record) teaches polysaccharide such as DEAE-dextran is suitable adjuvant for the vaccination of animals and humans (See column 5, lines 48-62, Abstract, in particular).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
March 25, 2002

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640